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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/618,596 07/17/00 MACINA

R DEX-0075

EXAMINER

HM12/0405

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ART UNIT

PAPER NUMBER

1642

*10*

DATE MAILED:

04/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

# Office Action Summary

Application No.

09/618,596

Applicant(s)

Macina And Sun

Examiner

Alana M. Harris, Ph. D.

Group Art Unit

1642



☒ Responsive to communication(s) filed on Jan 31, 2001

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-12 is/are pending in the application

Of the above, claim(s) 6 and 8-12 is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-5 and 7 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 8, filed Sept. 20, 2000.

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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## **DETAILED ACTION**

### ***Election/Restriction***

1. Applicant's election with traverse of Group I (claims 1-5 and 7) in Paper No.9 (filed January 31, 2001) is acknowledged. The traversal is on the grounds that it would not be an undue burden on the Examiner to search Groups I-VI. Applicants believe that a search for prior art for CSGs used diagnostic methods of Group I would also reveal art relating to additional uses for CSGs in methods of Groups II and IV-VI, as well as antibodies against these CSGs set forth in Group III. This is not found persuasive.

The argument that a search encompassing Groups I-VI is not found persuasive for the reasons set forth in the restriction requirement (Paper No. 7, mailed December 27, 2000). As to the question of burden of search, the claims of the 5 different method Groups are classified differently necessitating different searches in the U.S. Patent shoes. Further, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Clearly different searches and issues are involved in the examination of each group. For these reasons the restriction requirement is deemed to be proper and is adhered to.

The requirement is therefore made **FINAL**.

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2. Claims 1-12 are pending.

Claims 6 and 8-12, drawn to non-elected inventions are withdrawn from examination.

Claims 1-5 and 7 are examined on the merits.

***Claim Rejections - 35 U.S.C. § 112***

3. Claims 1-5 and 7 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1-5 and 7 are vague and indefinite in the recitation "CSG". "CSG" is an abbreviation whose identity is not well known in the art. The applicant is advised to amend the claims to include the full terminology.

***Claim Rejections - 35 U.S.C. § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Number 5,733,748 (filed June 6, 1995). U.S. Patent #5,733,748 discloses methods for diagnosing

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the presence of colon cancer and metastases of colon cancer in a patient (see Abstract; column 1, paragraph 1; bridging paragraph of columns 7 and 8). These methods are based on determining the levels of CSG in samples from a patient's cells, blood and saliva, for example (see column 8, lines 30-32; column 9, lines 17-20) and comparing the levels of CSG between colon cancer samples and non-diseased samples (see column 8, lines 10-16).

6. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/39419 (Document AD on IDS). WO 96/39419 discloses methods for diagnosing the presence of colon cancer and metastases of colon cancer in a patient (see Abstract; page 1, paragraph 1; page 14, paragraph 1). These methods are based on determining the levels of CSG in samples from a patient's cells, blood and saliva, for example (see page 14, last paragraph; page 15, first paragraph; page 34, second paragraph) and comparing the levels of CSG between colon cancer samples and non-diseased samples (see page 14, paragraph 2, sentence 4).

***Claim Rejections - 35 U.S.C. § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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8. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Number 5,733,748 (filed June 6, 1995) and WO 96/39419 (Document AD on IDS). The teachings of the recited patent and WO document have been listed above. Neither one of these references teach methods of staging colon cancer in a patient, monitoring colon cancer in a patient, nor monitoring a change in stage of colon cancer in a patient comprising determining CSG levels in samples and periodically comparing said levels with levels of a normal human control, wherein an increase of CSG levels may be indicative of a relapse, metastasis or progression.

However, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to implement the methods of staging and monitoring colon cancer in a patient for changes in staging as well as for the onset of metastasis considering the methods of diagnosing the presence of colon cancer and metastases have been well established. One of ordinary skill in the art would have been motivated to continue sampling CSG levels from a patient with colon cancer in order to establish a prognosis and chart the disease. Moreover, one of ordinary skill in the art would have had a reasonable expectation of success implementing the methods of staging and monitoring colon cancer since it had been well established in the diagnosis of cancer and methods involving the practice of comparing diseased CSG samples versus control samples in these methods since the time the claimed invention was made.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris whose telephone number is (703)306-5880. The examiner can normally be reached on Monday through Friday from 6:30 am to 4:00 pm, with alternate Fridays off. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703)308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703)308-0196.

Alana M. Harris, Ph.D.  
Patent Examiner, Group 1642  
April 4, 2001

  
SHEELA HUFF  
PRIMARY EXAMINER